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SUBTITLE: The Medical Implications of Intraocular Ballistic and Laser Protective Spectacles

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13. ABSTRACT *(Maximum 200*

PURPOSE: We designed a study to determine the effects of intraocular fragments of ballistic protective lenses, laser protective frontserts, and the laser absorbing dyes employed in the BLPS system. **BACKGROUND:** The intraocular toxicity of polycarbonate, the laser absorbing dyes, and the scratch resistant coatings employed in BLPS are largely unknown. Knowledge of these potential toxicities is important in establishing medical evacuation priorities and surgical management. **METHODS:** Fragments of the BLPS lenses, frontserts, and suspensions of the dyes were surgically implanted into the eyes of rabbits. The animals were randomized into ten groups including positive and negative controls. The animals were examined clinically and electrophysiologically prior to implantation and enucleation. They were euthanized at various intervals up to 26 weeks. **RESULTS:** Those eyes implanted with 3 λ frontsert fragments exhibited supernormal dark-adapted ERG b- wave amplitudes. Intraocular inflammation was significantly greater at early time points in both the clear polycarbonate and 3 λ groups. Those eyes injected with lambda 1 and lambda 3 absorbing dyes exhibited depressed dark-adapted ERG b-wave amplitudes. **CONCLUSIONS:** We have developed a reliable and reproducible system for evaluating the intraocular toxicities of ballistic and laser protective eyewear. The lambda 1 and lambda 3 absorbing dyes appear to interfere with normal retinal physiology at one week. These changes are consistent with the apparent toxicity noted in the studies employing BLPS frontsert fragments in which the fragment containing all three dyes produced significant ERG abnormalities at 1 to 2 weeks. The apparent early toxicity of the BLPS 3 λ frontsert fragments, as manifested in both the clinical exam and ERG, warrant high medical evacuation priority and urgent vitrectomy in cases of accidental intraocular implantation.

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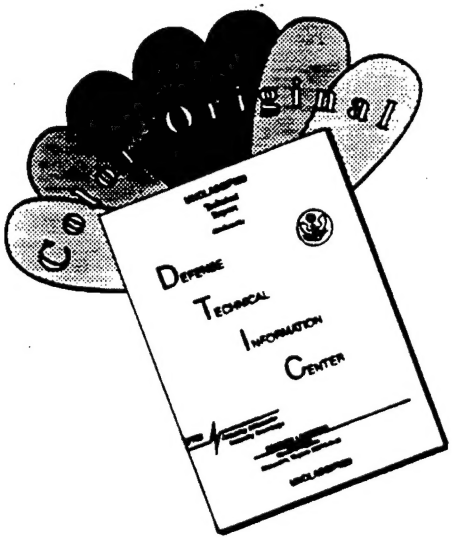

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Kristen Lee Roberts

15AUG96

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THE MEDICAL IMPLICATIONS OF INTRAOCULAR BALLISTIC AND LASER PROTECTIVE SPECTACLES (BLPS)

Cavallaro, Brian E., Hollifield, Rodney D., Ward, Thomas P., Wertz, Fleming D.

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PURPOSE

We designed a study to determine the effects of intraocular fragments of ballistic protective lenses and laser protective frontserts. Furthermore we evaluated the toxicity of the laser absorbing dyes employed in the the BLPS system.

BACKGROUND

The intraocular toxicity of polycarbonate, the laser absorbing dyes, and the scratch resistant coatings employed in BLPS are largely unknown. Knowledge of these potential toxicities is important in establishing medical evacuation priorities and surgical management.

METHODS

Fragments (0.4 mg) of the BLPS lenses and the frontserts were surgically implanted into eyes of Albino rabbits. The animals were randomized into six groups: clear polycarbonate lens; tinted polycarbonate lens; 2 wavelength (λ) protective frontsert; 3 λ protective frontsert; iron (positive control); and sham operated eyes (negative control). The animals were evaluated by clinical exam including intraocular pressure and bright-flash ERG prior to both fragment implantation and enucleation. The animals were euthanized at 1, 2, 4, and 26 weeks. An interim clinical exam was performed at 12 weeks on the 26 week animals. The enucleated eyes were examined and sectioned for histopathological evaluation. Suspensions of 100 ug of the dyes in 0.2 ml of Balanced Salt Solution (BSS) were injected into the mid-vitreous cavity of the right eye of Albino rabbits. Thirty-two animals were randomized onto four groups: 532 nm (lambda 1) absorbing dye ; 694 nm (lambda 2) absorbing dye ; 1064 nm (lambda 3) absorbing dye ; and BSS (vehicle). The animals were evaluated as noted above prior to intravitreal injection and at 2, 7, and 14 days thereafter. These animals were euthanized at 2 or 14 days post-injection. The eyes were enucleated, grossly examined, and sectioned for histopathological evaluation.

BLPS (Figure 1).

BLPS Fragments (Figure 2).

Fragment Surgical Technique (FIGURE 3): A) Following a partial superotemporal limbal peritomy, a 4 mm incision was created 3 mm posterior to the limbus. B) Any vitreous prolapsing from the wound was excised. C) The fragments were then placed within the vitreous cavity using intraocular foreign body forceps under direct visualization. D) The sclera was closed using 7-0

vicryl suture. After closing the conjunctiva, a 10 mg subconjunctival injection of gentamicin was administered.

RESULTS

FIGURE 4: Those eyes implanted with **3 λ frontsert** fragments exhibited supernormal **dark-adapted ERG b-wave amplitudes** when compared to sham operated eyes at 2 weeks (*$P<0.05$). Data presented as means. Error bars are omitted for clarity. $n=5$ at each point, except at 6 months, where $n=3$.

FIGURES 5: Anterior chamber flare and **vitreous cellular reaction** were significantly greater at early time points (≤ 2 weeks) in those eyes implanted with either **clear polycarbonate lens** or **3 λ frontsert** fragments when compared to negative controls (* $P<0.05$).

FIGURE 6: Fundus photographs of **clear polycarbonate lens** (A) and **2 λ frontsert** (B) fragments at two weeks, demonstrating fragment location within the vitreous cavity.

FIGURE 7: Photograph of a gross specimen containing a **2 λ frontsert** fragment. Enucleation occurred at two weeks. Note the flakes of frontsert coatings within the vitreous (arrow).

FIGURE 8: Photomicrograph of a Hematoxylin and Eosin stained section of an eye which had been implanted with a **3 λ frontsert** fragment. Enucleation occurred at two weeks. Original magnification 15X. Note the fibrous encapsulation of the frontsert fragment. **F**-fragment; **AC**-anterior chamber; **V**-vitreous; **S**-sclera.

Those eyes injected with the lambda 1 and lambda 3 absorbing dyes exhibited depressed dark-adapted ERG b-wave amplitudes at 7 days ($P=0.052$) when compared to the noninjected fellow eyes.

DISCUSSION

Supernormal ERG a- and b-wave amplitudes have been reported to occur early in toxic conditions such as metallosis bulbi (1). Components of the BLPS system which could potentially cause intraocular toxicity include polycarbonate, silica-based scratch-resistant coatings, acrylic

dye carriers, and protective dyes. Intraocular polycarbonate has been shown to be inert (2). Unwetted silicone intraocular lenses have been reported to stimulate an inflammatory encapsulating response (3). Intraocular toxicities of acrylic carriers and protective dyes are unknown. Radical formation is a potential mechanism of injury (4). Compounds related to the laser-protective dyes have been shown to generate radicals (5,6,7).

CONCLUSIONS

We have developed a reliable and reproducible system for evaluating the intraocular toxicities of ballistic and laser protective eyewear.

The lambda 1 and lambda 3 absorbing dyes appear to interfere with normal retinal physiology at one week. These changes are consistent with the apparent toxicity noted in the studies employing BLPS frontsert fragments in which the fragment containing all three dyes produced significant ERG abnormalities at 1 to 2 weeks.

The apparent early toxicity of the BLPS 3 λ frontsert fragments, as manifested in both the clinical exam and ERG, warrant high medical evacuation priority and urgent vitrectomy in cases of accidental intraocular implantation.

Further studies are needed to elucidate the pathophysiological mechanisms involved.

DISCLAIMER

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of Army or Department of Defense.

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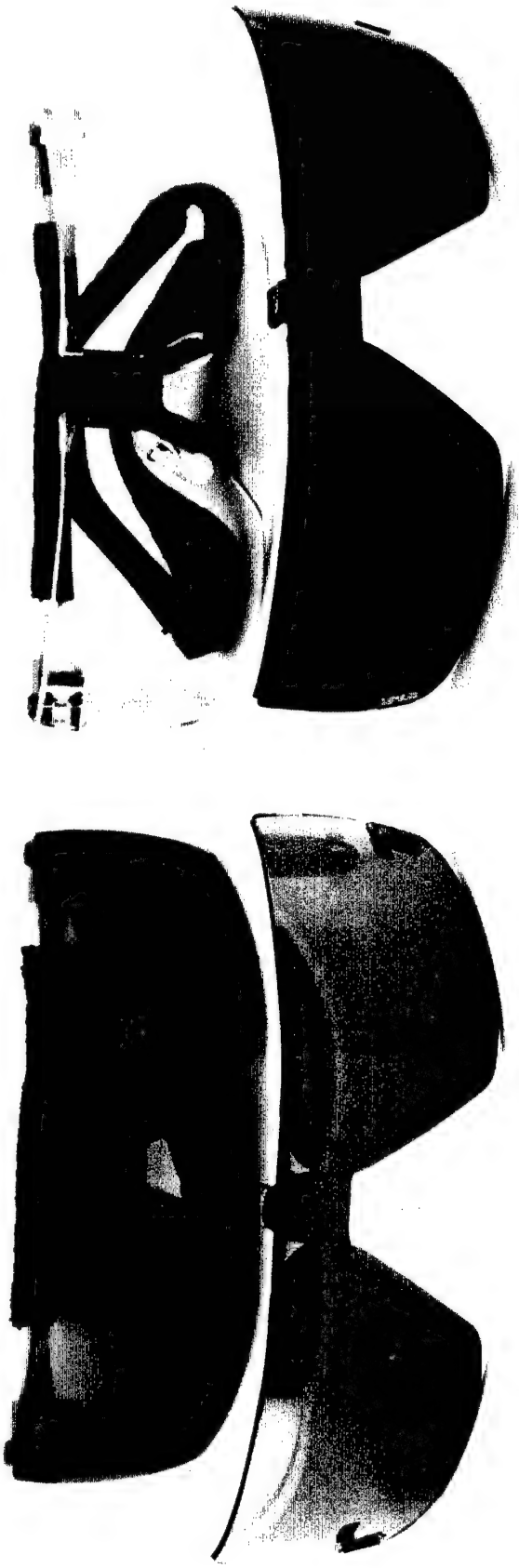

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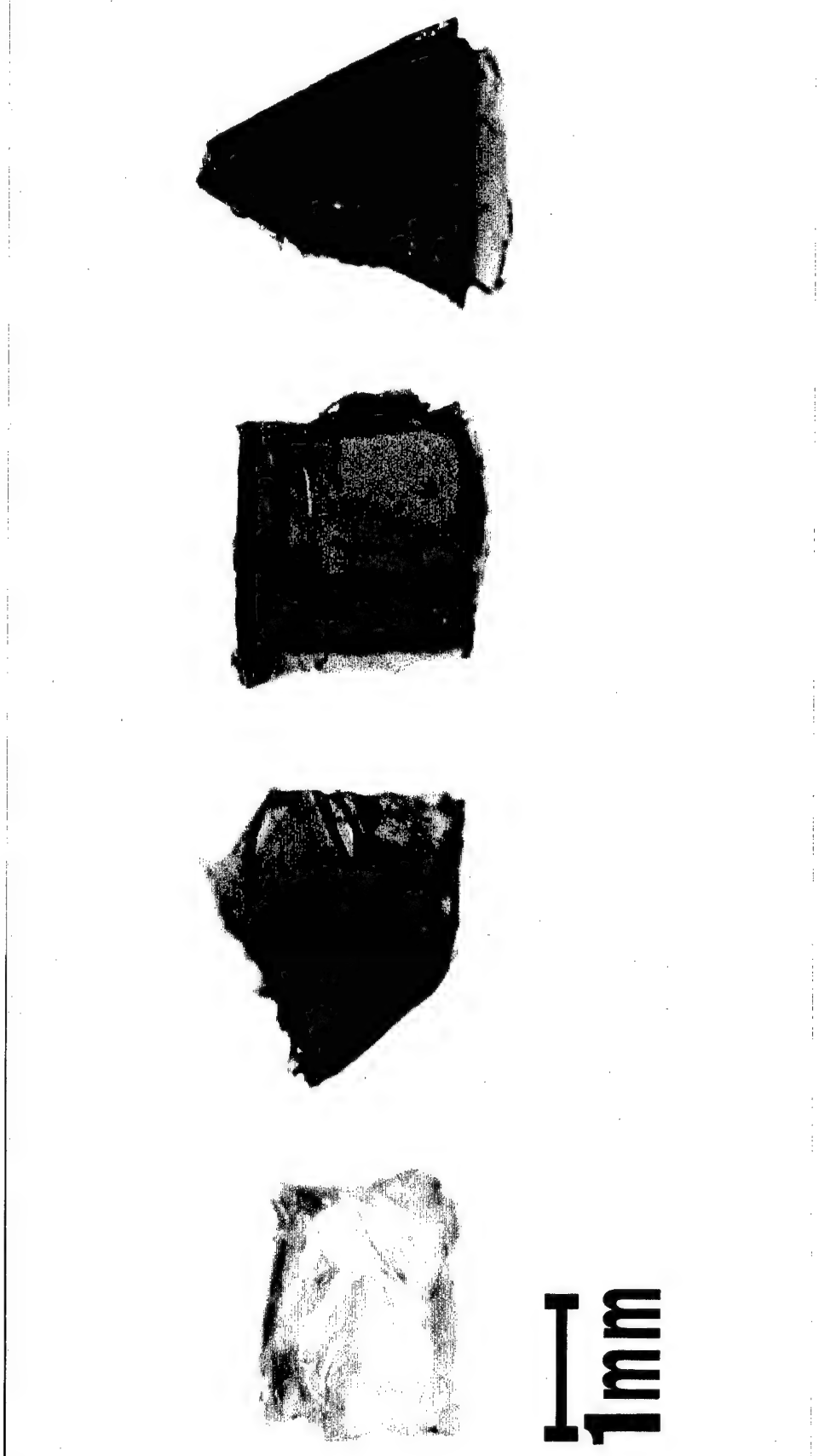

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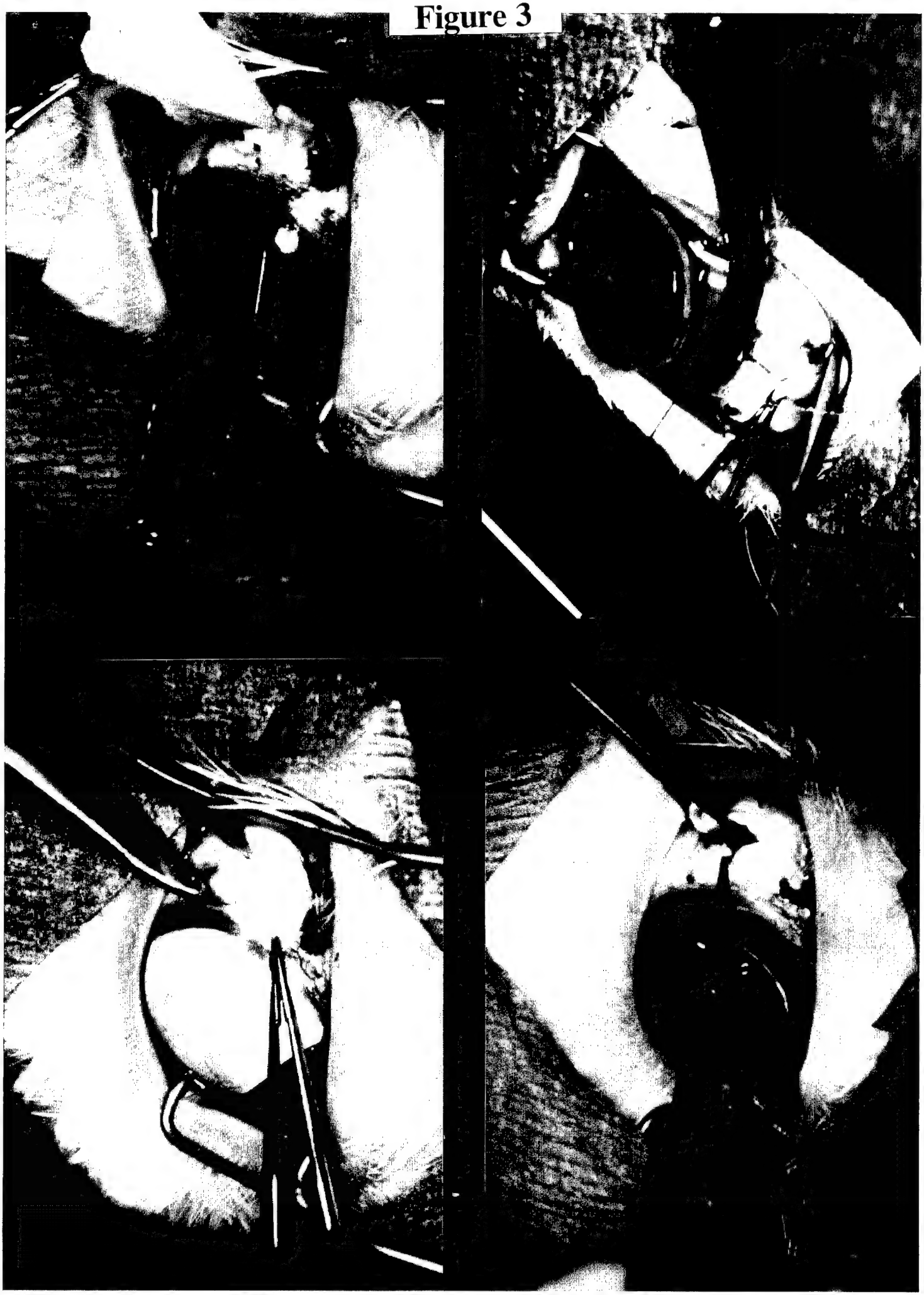

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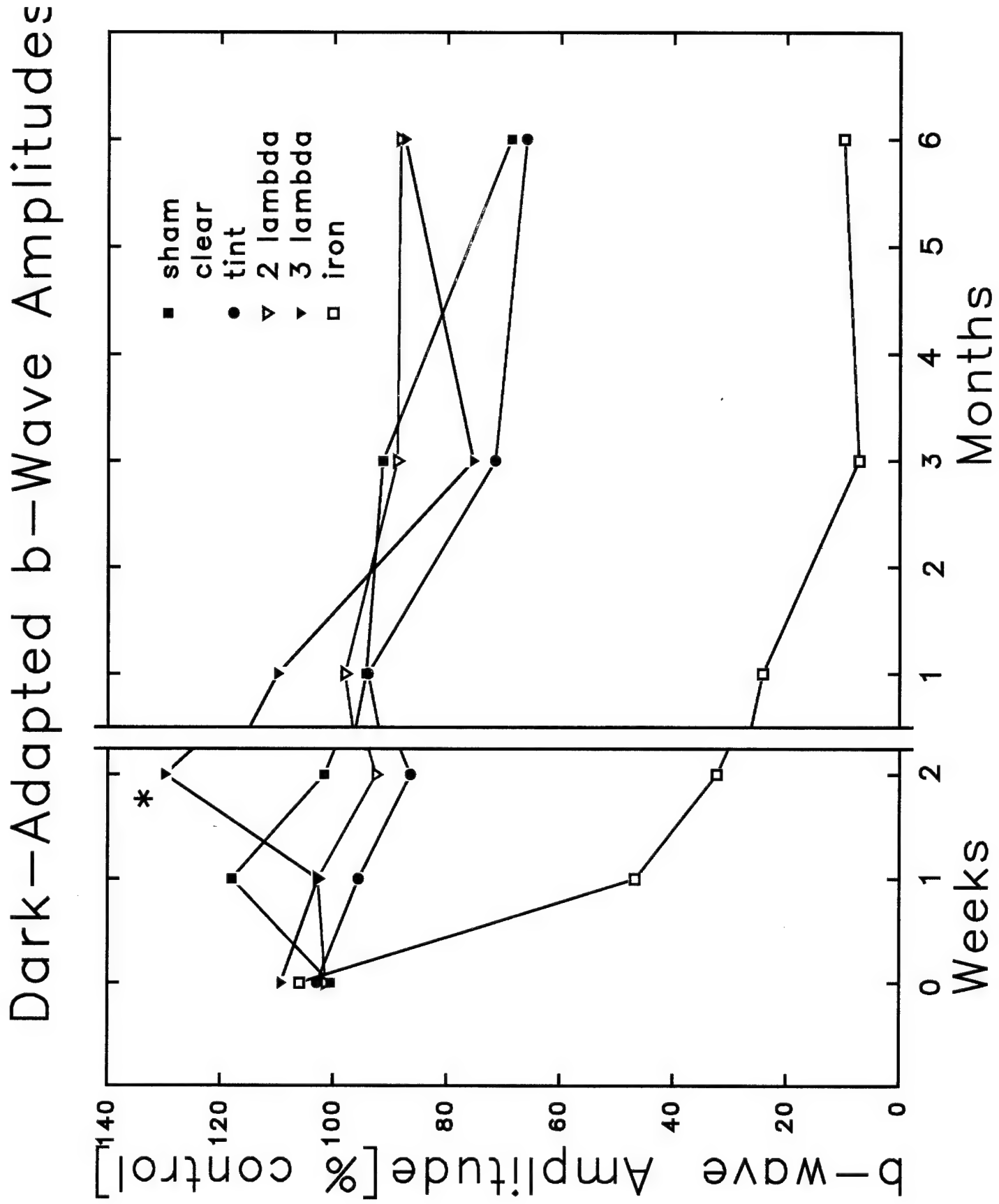
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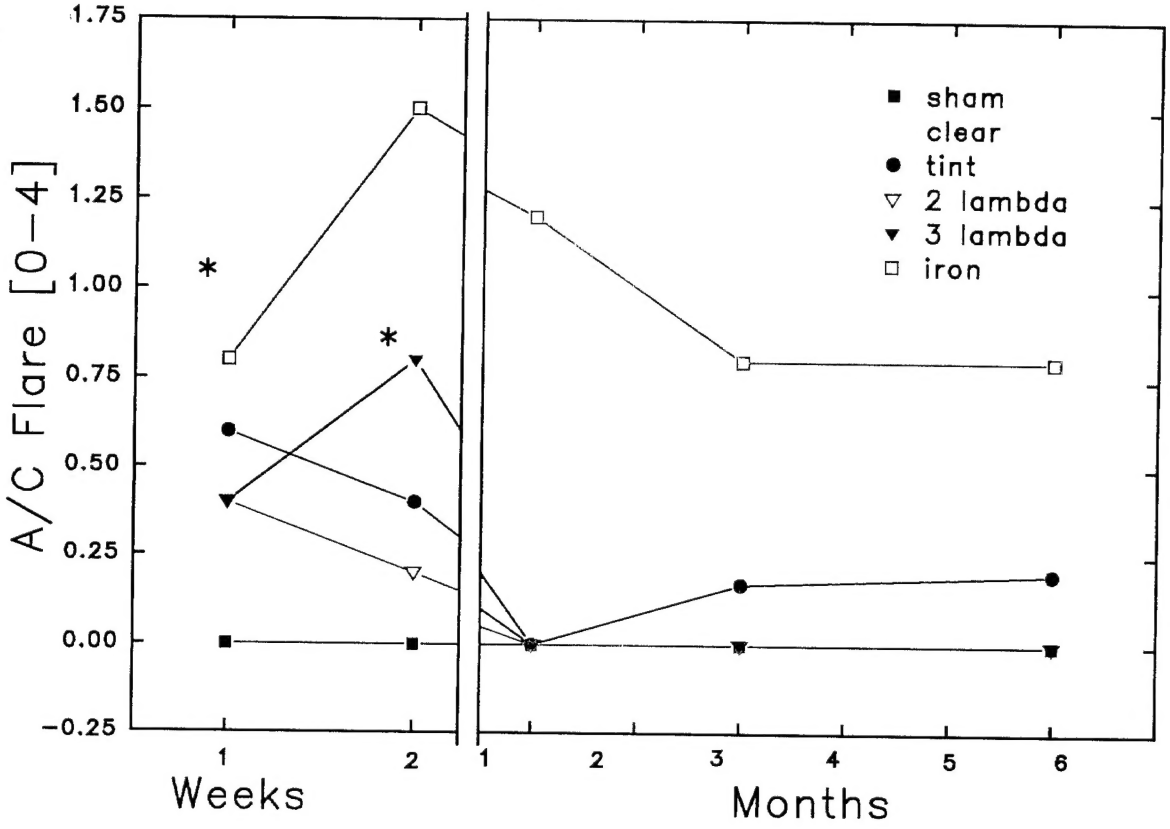
Months

Figure 5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Months

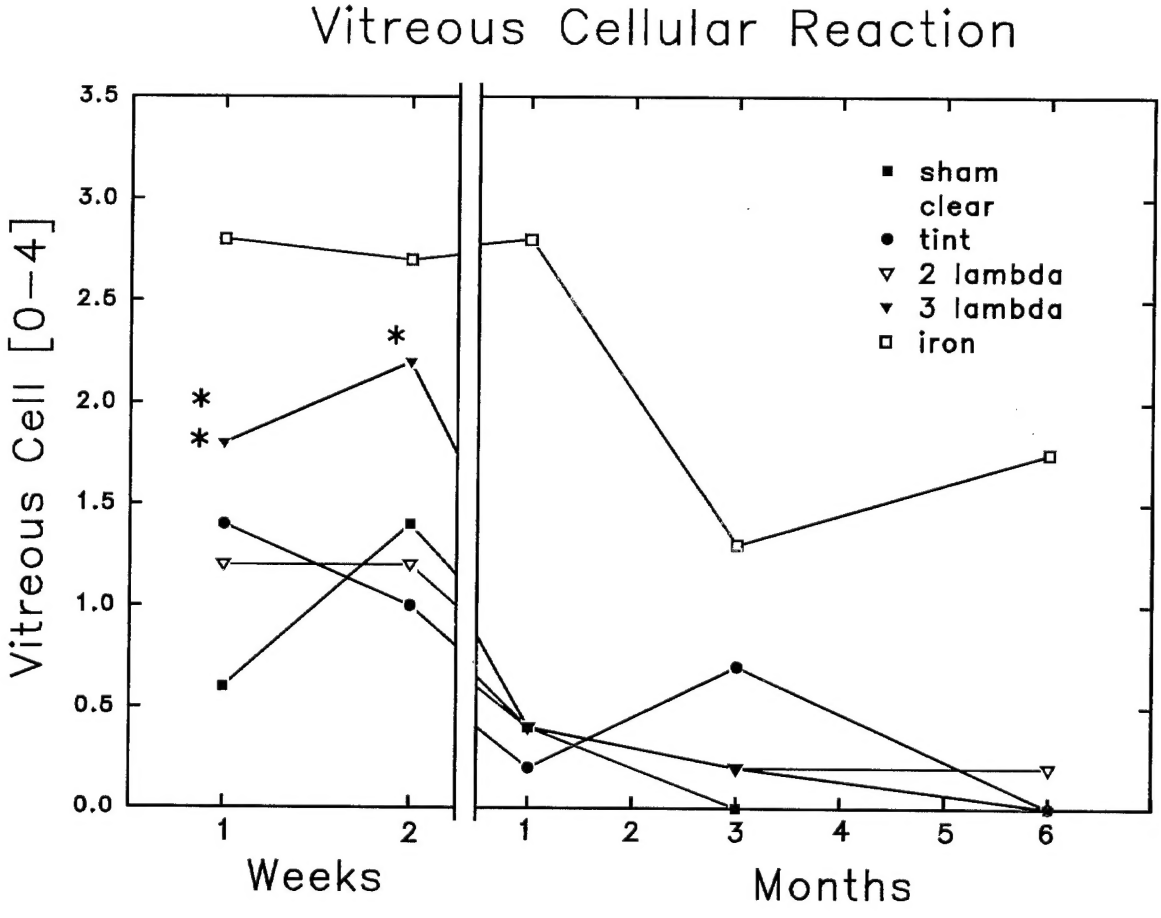
Vitreous Cellular Reaction
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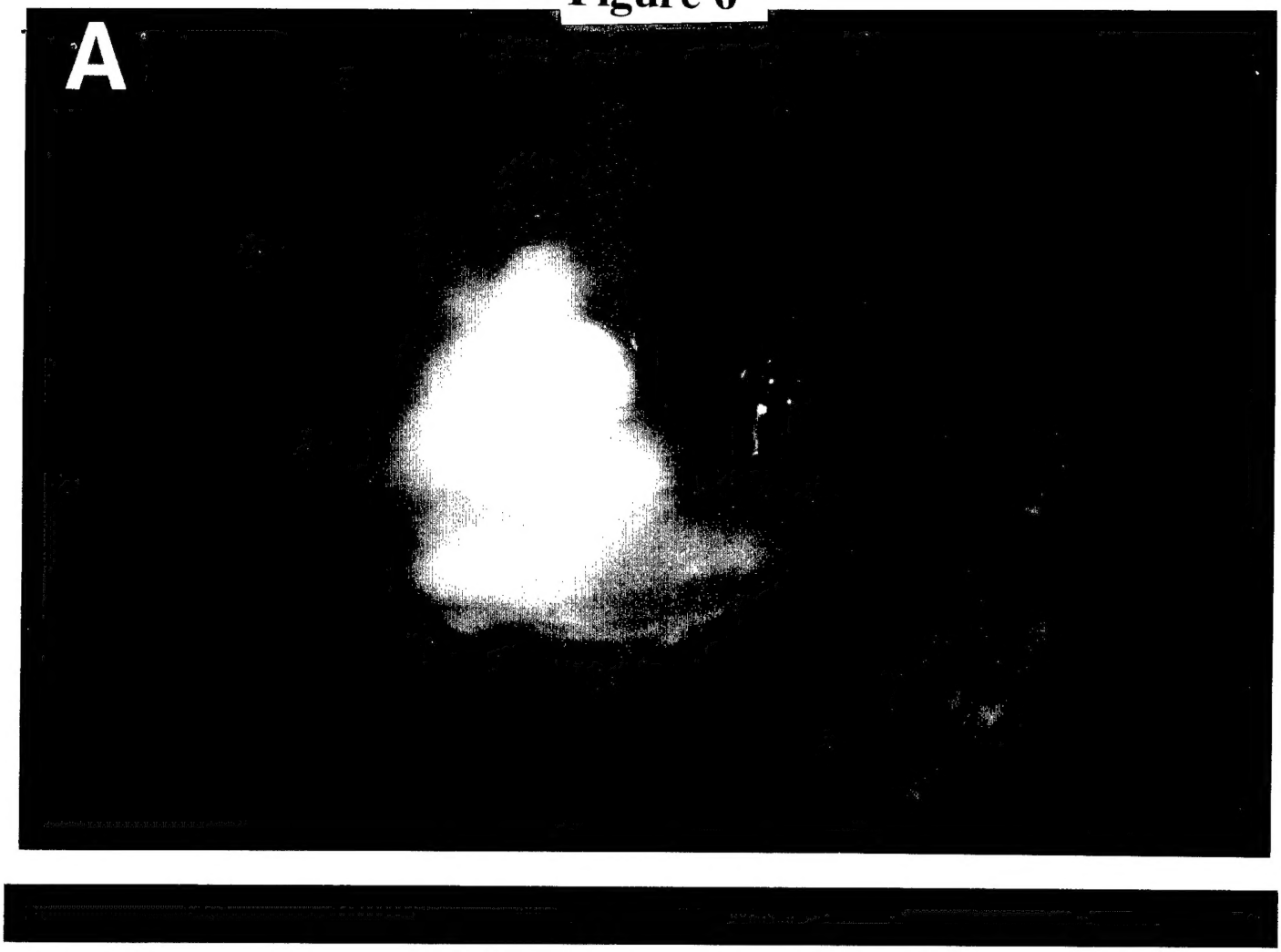
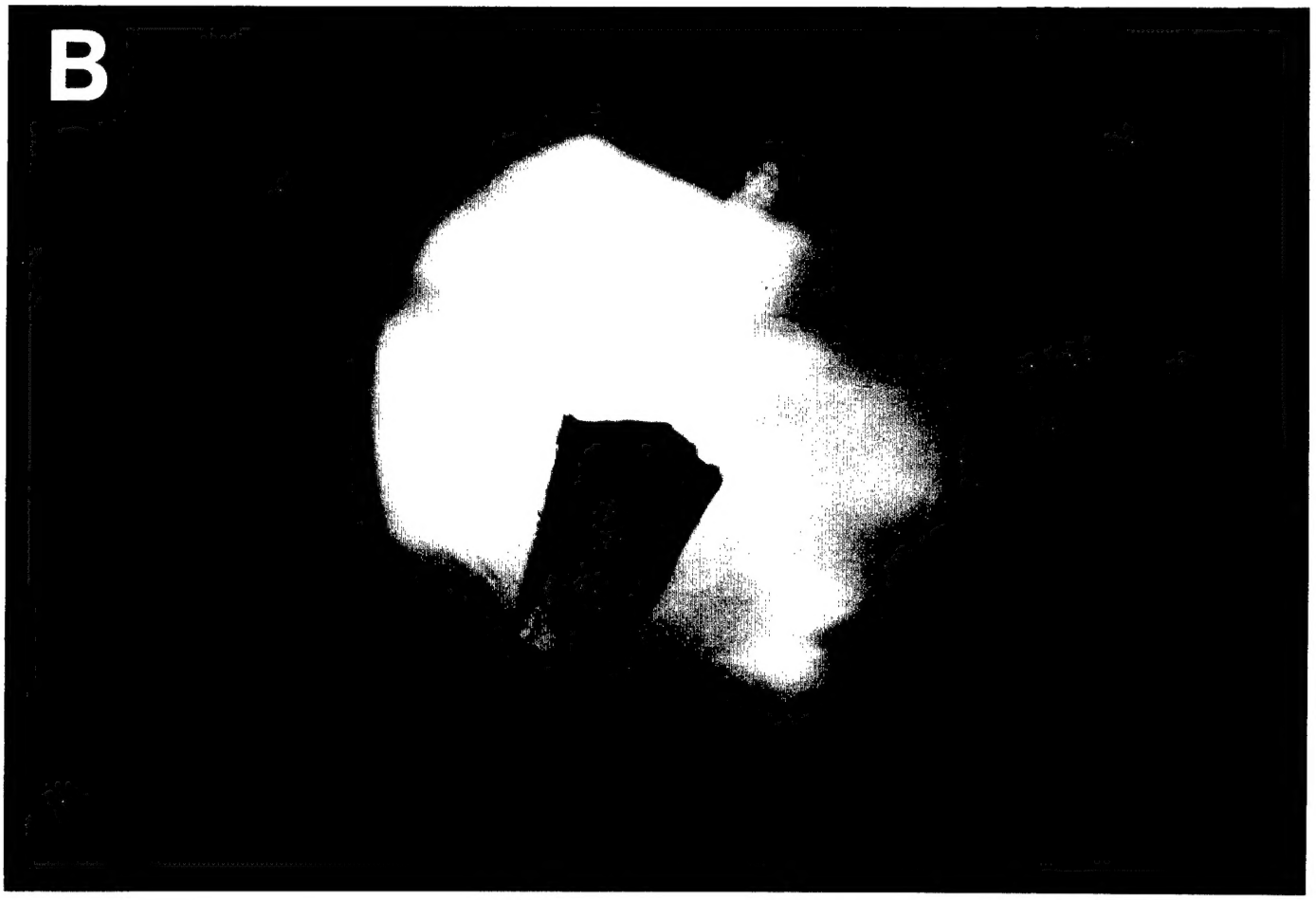
Figure 6





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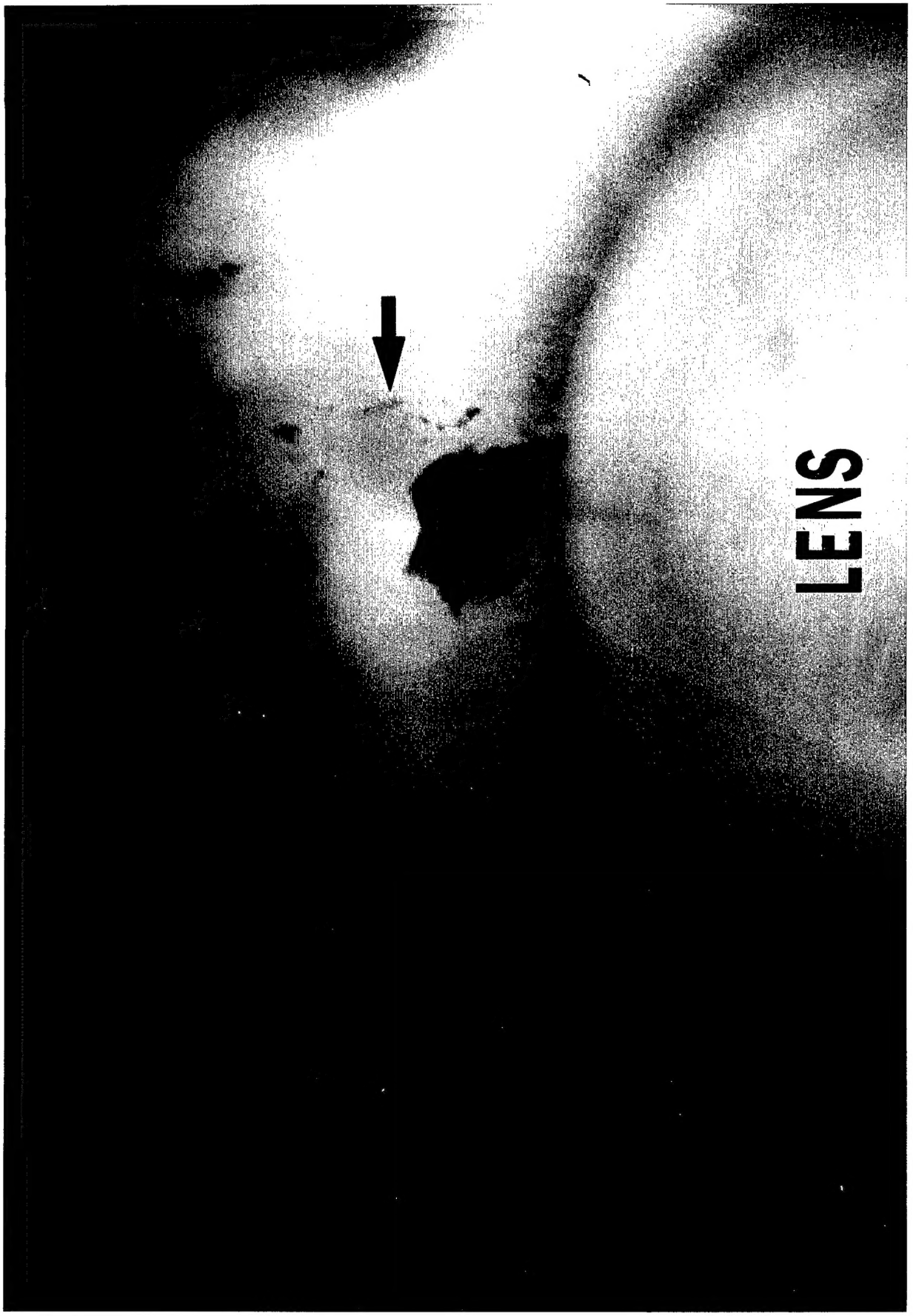

Figure 8